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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/743,384	12/23/2003	Richard Eric Rothman	001107.000412	7753
<div>22907      7590      10/04/2007</div> <div>BANNER &amp; WITCOFF, LTD.</div> <div>1100 13th STREET, N.W.</div> <div>SUITE 1200</div> <div>WASHINGTON, DC 20005-4051</div>				
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			<div>ART UNIT</div> <div>1637</div>	<div>PAPER NUMBER</div>
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/743,384	Applicant(s) ROTHMAN ET AL.	
	Examiner Cynthia B. Wilder, Ph.D.	Art Unit 1637	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 30 July 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/30/2007 has been entered. Claims 1-3, 16-18 have been amended. Claims 43-52 have been canceled. Claims 1-42 are pending.

### ***New Ground(s) of Rejections***

#### ***Claim Rejections - 35 USC § 112***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(a) Claims 1-42 are vague and confusing overall. Specifically, it is unclear in the claims 1 and 16 as to what regions the primes and probes are hybridizing to in order to distinguish between eubacteria species. It is confusing as to what constitutes the conserved regions of the eubacteria species and even more so, what constitutes the first, second, third, fourth, and fifth divergent regions of an eubacteria species as no

specific sequences for those regions have been identified. Accordingly, a clear interpretation of Applicant's intent cannot be ascertained.

### ***Claim Interpretation***

4. In Applicant's remarks filed on 7/30/2007, Applicant states that neither *S. aureus* nor *B. Japonicum* must be present in the sample for the method to operate. Applicant states that these species are merely used to provide reference sequences in comparison to which the conserved and divergent regions of rRNA genes are defined. Applicant states that the claims do not require hybridization of the first or second probe to *S. aureus* or to *B. Japonicum*. Accordingly, for the purpose of application of prior art, the Examiner is interpreting the claims as not requiring hybridization to *S. aureus* or to *B. Japonicum*. The examiner is interpreting the "conserved" and "divergent" regions as being inherent in eubacterial species comprising 16S rRNA and represents "any sequence(s)" found in the 16S rRNA gene of eubacteria species.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein

were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-3, 7-11, 13-18, 22-26 and 28-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al (Journal of Clinical Microbiology, vol. 32, no. 2, pages 335-351, Feb. 1994) and Reischl et al (Journal of Clinical Microbiology, Vol. 38, No. 6, pages 2429-2433, June 2000). Regarding claims 1-3, 16-18 and 33-42, Greisen et al teach a method for detecting eubacterial and determining species of said eubacteria in a sample, comprising: providing universal bacterial primers that correspond to regions of the 16S rRNA gene which are highly conserved among divergent groups of eubacteria and therefore would be expected to amplify DNA from most pathogenic bacteria; providing universal bacterial probe designed from a conserved region of the 16S rRNA gene, which is located between the universal primers (see pages 340-341, sections entitled "Specificity of universal bacterial primers" and "Universal bacterial probe" and "Universal gram-positive and gram-negative probes") and performing DNA amplification (page 336, section entitled "DNA amplification") and probe hybridization (page 338). Greisen et al teach that the primers locations were chosen to be relatively specific for eubacterial genes at the 3' ends (page 341). Thus Greisen inherently meet the limitations of the claims for the conserved and divergent regions of the eubacterial species as recited in the claims. The bindings to the various

divergent regions are deemed inherent by the universal primers and probes of Greisen et al.

Greisen et al do not expressly teach wherein the universal primers and universal probes are used in real-time fluorescence PCR. Reischl et al teach a duplex LightCycler PCR assay to detection of *Staphylococcus aureus* strains and other related bacterial species (abstract). Reischl et al teach wherein the method comprises providing oligonucleotide primers and fluorescence-labeled hybridization probes, designed for amplification and sequence-specific detection of fragments within *mecA* and *S. aureus* specific genomic markers (page 2430, col. 2). Reischl et al teach that this duplexes approach, containing four different primers oligonucleotides and four different hybridization probes within a single capillary, revealed identical detection limits. Reischl et al teach that significant formation of primer dimers or secondary structures or other cross-reactions between oligonucleotide components, which frequently interfere with the analytical sensitivity of multiplex PCR approaches are therefore unlikely in this particular assay (bottom of page 2432, col. 2 bridging page 2432, col. 1 first five lines). Reischl et al further teach that the LightCycler device used in the method allows for ultrarapid thermal cycling and online monitoring of the amount of specific PCR products present in an amplification mixture (page 2429, col. 2, lines 14-17).

Reischl et al teach that the LightCycler HybProbe concept avoids the application of time-consuming and laborious post-amplification procedures (bottom of page 2432, col. 1). Reischl et al teach that due to its compact and reliable nature, the duplex PCR assay proved to be a valuable tool for the rapid identification of *S. aureus* isolates in the

environment of a routine microbiological laboratory setting 9bottom of page 2432, col. 1 to top of col.2). Reischl et al teach that in combination with the simple boiling protocol for template DNA preparation, it can be easily integrated into the workflow of any diagnostic laboratory (page 2432, col. 2).

Therefore, one of ordinary skill in the art would have been motivated to have modified the PCR eubacterial speciation method of Greisen to encompass a real-time fluorescence PCR method as taught by Reischl instead of the traditional PCR amplification reaction based on the numerous advantages taught by Reischl et al that the LightCycler PCR assay allows for ultra-rapid thermal cycling and online monitoring of the amount of specific PCR products present in an amplification mixture, the method alleviates significant formation of primer dimers or secondary structures or other cross-reactions between oligonucleotide components and the method avoids the application of time-consuming and laborious post-amplification procedures.

Regarding claim 7-8, 10-11, 22-23 and 25-26, Greisen et al teach wherein the sample is for the detection of bacteria in blood, cerebrospinal fluid and other normally sterile body fluids, which includes urine (page 335, col. 2, last 6 lines).

Regarding claims 9 and 24, Greisen et al teach wherein the sample was treated to extract DNA from cells (see page 336, "DNA Isolation").

Regarding claims 13-15, 28-30, Reischl et al teach wherein the segment amplified is about 179 base pairs (see page 2430, col. 2).

Regarding claim 31 and 32, Greisen et al inherently teach wherein the conserved region is at least 80% identical in over 14 eubacterial species (see page 340 and 345 and Table 2).

***Claim Rejections - 35 USC § 103***

8. Claims 4, 12, 19 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al in view of Reischl et al as previously applied above, in view of Abrams et al (6238927, effective filing date October 1998) and Iversen (6677153, effective filing date November 1999) and further in view of Buck et al (Biotechniques vol. 27, No. 3, pages 528-536, 1999). Regarding claims 4, 12, 19 and 27, Greisen et al in view of Reischl et al teach a method for detecting and determining species of eubacteria in a sample use a real time fluorescence PCR assay as previously described above.

The method of Greisen et al in view of Reischl et al differs from the instant invention in that the references do not expressly teach wherein the segment of *S. aureus* 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 1 and 2.

Abrams et al teach a primer sequence that is 100% identical to the sequence of SEQ ID NO: 1 (see SEQ ID NO: 1 at col. 13 and 14), wherein said sequence is used in a method for detection of a target nucleic acid sequence.

Iversen teaches a primer sequence that is 100% identical to the sequence of SEQ ID NO: 2 (see SEQ ID NO: 25 at col. 63 and 64), wherein said sequence is used in a method for detection of a target nucleic acid sequence.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the



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Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious.

Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Abrams et al and Iversen, which are 100% derived from sequences expressly suggested by the prior art of and known in the prior art as useful for primers and probes for detecting a specific target, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

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With regard to the issue of reasonable expectation of success in using such equivalents, Buck et al expressly provides a general teaching of evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18-mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95-control primers functioned, which represent 1/3 of all possible primers in the target region.

This clearly shows that every primer would have a reasonable expectation of success.

***Claim Rejections - 35 USC § 103***

9. Claims 5 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al in view of Reischl et al as previously applied above, in view of Kunsch et al (6593114, effective filing date January 1996) and further in view of Buck et al (Biotechniques vol. 27, No. 3, pages 528-536, 1999). Regarding claims 5 and 20, Greisen et al in view of Reischl et al teach a method for detecting and determining species of eubacteria in a sample use a real time fluorescence PCR assay as previously described above.

The method of Greisen et al in view of Reischl et al differs from the instant invention in that the references do not expressly teach wherein the segment of *S. aureus* 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 3.

Kunsch et al teach a sequence that is 95.7% identical to the sequence of SEQ ID NO: 3:

SEQ ID NO: 3	CACGAGCTGACGACARCCATGCA
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Kunsch et al (SEQ ID NO: 5124) CACGAGCTGACGACAACCATGCA, wherein said sequence is used to detect *S. aureus* strains.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion

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to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Kunsch et al, which is 95.7% identical to and derived from sequences expressly suggested by the prior art and known in the prior art as useful for primers and probes for detecting a specific target, such as *S. aureus*, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

With regard to the issue of reasonable expectation of success in using such equivalents, Buck et al expressly provides a general teaching of evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page

530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18-mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95-control primers functioned, which represent 1/3 of all possible primers in the target region.

This clearly shows that every primer would have a reasonable expectation of success.

### ***Claim Rejections - 35 USC § 103***

10. Claims 6 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greisen et al in view of Reischl et al as previously applied above, in view of Barry et al (EP 0 395 295) and further in view of Buck et al (Biotechniques vol. 27, No. 3, pages 528-536, 1999). Regarding claims 4, 12, 19 and 27, Greisen et al in view of Reischl et al teach a method for detecting and determining species of eubacteria in a sample use a real time fluorescence PCR assay as previously described above.

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The method of Greisen et al in view of Reischl et al differs from the instant invention in that the references do not expressly teach wherein the segment of *S. aureus* 16 rRNA gene comprises the nucleotides as shown in SEQ ID NO: 4

Barry et al teach an *S. aureus* probe sequence that is 100% identical to the sequence of SEQ ID NO: 4 (see alignment below).

SEQ ID NO: 4      1 CCTTTGACAACCTCTAGAGATAGAGCCTTCCC 31  
EP 0395295      13 CCTTTGACAACCTCTAGAGATAGAGCCTTCCC 43.

In the recent court decision *In Re Deuel* 34 USPQ 2d 1210 (Fed. Cir. 1995), the Court of Appeals for the Federal Circuit determined that the existence of a general method of identifying a specific DNA does not make the specific DNA obvious. Regarding structural or functional homologs, however, the Court stated,

"Normally, a *prima facie* case of obviousness is based upon structural similarity, i.e., an established structural relationship between a prior art compound and the claimed compound. Structural relationships may provide the requisite motivation or suggestion to modify known compounds to obtain new compounds. For example, a prior art compound may suggest its homologs because homologs often have similar properties and therefore chemists of ordinary skill would ordinarily contemplate making them to try to obtain compounds with improved properties (see page 9, paragraph 4 of attached ref)."

Since the claimed primers and probes simply represent structural homologs of the oligonucleotides taught by Barry et al, which is 100% derived from sequences expressly suggested by the prior art of and known in the prior art as useful for primers and probes for detecting a specific target, and concerning which a biochemist of ordinary skill would attempt to obtain alternate compounds with improved properties, the claimed primers and probes are *prima facie* obvious over the cited references in the absence of secondary considerations.

With regard to the issue of equivalence of the primers, MPEP 2144.06 notes "Substituting equivalents known for the same purpose. In order to rely on equivalence as a rationale supporting an obviousness rejection, the equivalency must be recognized in the prior art, and cannot be based on applicant's disclosure or the mere fact that the components at issue are functional or mechanical equivalents. An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious. *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982)."

With regard to the issue of reasonable expectation of success in using such equivalents, Buck et al expressly provides a general teaching of evidence of the equivalence of primers. Specifically, Buck invited primer submissions from a number of labs (39) (page 532, column 3), with 69 different primers being submitted (see page 530, column 1). Buck also tested 95 primers spaced at 3 nucleotide intervals along the entire sequence at issue, thereby testing more than 1/3 of all possible 18-mer primers on the 300 base pair sequence (see page 530, column 1). When Buck tested each of the primers selected by the methods of the different labs, Buck found that EVERY SINGLE PRIMER worked (see page 533, column 1). Only one primer ever failed, No. 8, and that primer functioned when repeated. Further, EVERY SINGLE CONTROL PRIMER functioned as well (see page 533, column 1). Buck expressly states "The results of the empirical sequencing analysis were surprising in that nearly all of the primers yielded data of extremely high quality (page 535, column 2)." Therefore, Buck provides direct evidence that all primers would be expected to function, and in

particular, all primers selected according to the ordinary criteria, however different, used by 39 different laboratories. It is particularly striking that all 95-control primers functioned, which represent 1/3 of all possible primers in the target region.

This clearly shows that every primer would have a reasonable expectation of success.

### ***Conclusion***

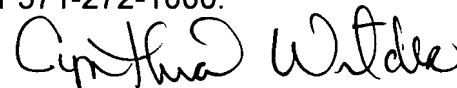
11. No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Cynthia B. Wilder, Ph.D.

Patent Examiner

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9/11/2007